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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,158	XUE, BOB BAOGUO	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *4,5,7-14 and 17-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,15,16 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-12, 15 and 16, and SEQ ID No. 1, in the reply filed on 5-5-09 is acknowledged. The traversal is on the ground(s) that there would not be undue burden for Examiner to search subsequences of SEQ ID No. 1, such as those listed in claim 12. This is not found persuasive because the amino acid sequences of SEQ ID Nos. 13-32 represent different open reading frames encoding different proteins that lack common properties and have different functions and uses. SEQ ID Nos. 3-12 represents oligonucleotide primer sequences that have different uses from the sequence of SEQ ID No. 1 that encodes a protein. Examination of various SEQ ID numbers would impose serious search burden on examiner. The polynucleotide sequence claimed in the patent application has become more complex and more full-length open reading frame. The sequence database, such as GenBank, has exploded to almost 100 folds in the number of nucleotides in 2006 as compared to that in 1996. These factors exacerbate the search and examination burden faced by the Office. There would be serious burden for examiner to search all of the sequences of SEQ ID Nos. 2-12 and the sequences listed in claim 12 (SEQ ID Nos. 13-32).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13, 14 and 17-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-5-09.

Applicant's amendment filed 5-5-09 has been entered. Claim 27 has been added. It should be noted that the claims filed 5-4-06 are the most recently filed claims in the prosecution history of the instant application, therefore, those claims (claims 1-23) are considered in the Restriction Requirement mailed 3-31-09. Therefore, claim 27 is renumbered to be claim 24. The claims presented in the amendment filed 5-5-09 are not the same as the claims filed on 5-4-06. Applicant is required to amend the claims to be consistent with the claims filed on 5-4-06. Claims 1-24 are pending. Since claims 4 and 5 read on SEQ ID Nos. 3-8 and 10-12 and claims 7-12 read on SEQ ID Nos. 2 and 13-32, which is not the elected SEQ ID No. 1, therefore, claims 4, 5 and 7-12 will NOT be examined at this time. Claims 1-3, 6, 15, 16 and newly added 24, and SEQ ID No. 1 are under consideration.

Specification

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there is no sequence identifier for the nucleotide sequences in Figures 5 and 6 or in the "DESCRIPTION OF THE FIGURES". Each nucleotide sequence is required to have a sequence identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 15, 16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "MNTF" in claim 1 is vague and renders the claim indefinite. The term "MNTF" in an abbreviation that can stand for various meanings. It is unclear what meaning is intended in the claim. Claims 2, 15, 16 and 24 depend from claim 1 but fail to clarify the indefiniteness.

The phrase "a control sequence compatible with a desired host vector" in claim 15 is vague and renders the claim indefinite. It is unclear as to the metes and bounds of what would be considered "compatible with a desired host vector". It is unclear what kind of control sequence is "compatible with a desired host vector". It is also unclear what kind of "host vector" is intended. Claim 16 depends from claim 15 but fails to clarify the indefiniteness.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

The claims read on a polynucleotide comprising at least 10 consecutive nucleotides of SEQ ID No. 1 or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed partial sequence of SEQ ID No. 1. The claims encompass polynucleotide sequences that differ from the fragment sequence of SEQ ID No. 1 at the 5' and 3' ends and the polynucleotide sequences can differ dramatically from the sequence of SEQ ID No. 1. The encoded amino acid sequence could differ dramatically or totally different from the amino acid sequence encoded by SEQ ID No. 1, i. e. human MNTF protein, or no protein is encoded by the claimed polynucleotide sequences at all. The scope of the claims includes various unknown and unidentified polynucleotides that either encode a protein with unknown biological function or not encode a protein at all.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 111 1, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1 117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

The specification only describes the nucleotide sequence of SEQ ID No. 1. In the instant case the genus of MNTF associated polynucleotide sequences encompassed by the claims lack a written description. The specification fails to describe what DNA molecules other than the nucleotide sequence of SEQ ID No. 1 fall into this genus and it was unknown as of Applicants' effective filing date that any of these DNA molecules would have the property of encoding a human MNTF protein having the same structural and functional properties as that encoded by SEQ ID No. 1. There is no evidence on the record of a relationship between the structures of the nucleotide sequences coding for any MNTF associated gene product and the nucleotide sequence coding for human MNTF protein that would provide any reliable information about the structure of DNA molecules within the genus. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor has possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotide sequences, and therefore conception is not achieved until reduction to practice has occurred regardless of the complexity

or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by any member of the genus of genes encoding a MNTF associated gene product other than the described nucleotide sequence of SEQ ID No. 1. Therefore, only the nucleotide sequence of SEQ ID No. 1, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112 first paragraph. Applicants were not in possession, at the time of the invention, of the nucleic acid sequences encoding various MNTF associated proteins other than the described sequence of SEQ ID No. 1. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

7. Claims 2, 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide sequence comprising the sequence of SEQ ID No. 1, does not reasonably provide enablement for a polynucleotide sequence comprising at least 10 consecutive nucleotides of SEQ ID No. 1 or comprising a fragment of SEQ ID No. 1 containing at least one nucleotide selected from the listed partial sequence of SEQ ID No. 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considered whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirement, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d at 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention with function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raises and discussed based on the state of knowledge pertinent to an art at

the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

The claims read on a polynucleotide comprising at least 10 consecutive nucleotides of SEQ ID No. 1 or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed partial sequence of SEQ ID No. 1. The claims encompass polynucleotide sequences that differ from the fragment sequence of SEQ ID No. 1 at the 5' and 3' ends and the polynucleotide sequences can differ dramatically from the sequence of SEQ ID No. 1. The specification discloses the nucleotide sequence of SEQ ID No. 1. As discussed above, it is apparent that applicants do NOT have possession of any nucleotide sequence other than the disclosed SEQ ID No. 1. Absent the possession of the claimed polynucleotide sequences, one skilled in the art at the time of the invention would not know how to use said claimed polynucleotide sequences.

The specification fails to provide adequate guidance and evidence for the biological function of the protein encoded by the claimed MNTF associated polynucleotide sequences and for how to use the claimed polynucleotide sequences. The amino acid sequence encoded by the

claimed polynucleotide sequences could differ dramatically or totally different from the amino acid sequence encoded by SEQ ID No. 1, i. e. human MNTF protein, or no protein is encoded by the claimed polynucleotide sequences at all. The scope of the claims includes various unknown and unidentified polynucleotides that either encode a protein with unknown biological function or not encode a protein at all. There is no evidence of record that shows the protein encoded by the claimed polynucleotide has the biological activity of MNTF protein. Absent specific guidance, one skilled in the art at the time of the invention would not know how to use the claimed polynucleotide.

It was known in the art that the amino acid sequence of a polypeptide determines its structural and functional properties (including half-life), and predictability of which amino acid(s) can be removed from or added to a polypeptide's sequence and still result in similar or higher activity or result in stabilization of the protein is extremely complex, and well outside the realm of routine experimentation. Kaye et al., 1990 (Proc. Natl. Acad. Sci. USA, Vol. 87, pp. 6922-6926) discloses that a single amino acid substitution results in a retinoblastoma protein defective in phosphorylation and oncoprotein binding (e.g. title). Skolnick et al., 2000 (Trends in Biotech, Vol. 18, p. 34-39) states "Sequence-based methods for function prediction are inadequate because of the multifunctional nature of proteins. However, just knowing the structure of the protein is also insufficient for prediction of multiple functional sites. Structural descriptors for protein functional sites are crucial for unlocking the secrets in both the sequence and structural-genomics projects" (e.g. abstract). Skolnick further states that "Knowing a protein's structure does not necessarily tell you its function" and "Because proteins can have similar folds but different functions, determining the structure of a protein may or may not tell

you something about its function" (e.g. p. 36, box 2). Tomasinsig et al., 2005 (Current Protein and Peptide Science, Vol. 6, p. 23-34) reports that cathelicidins family proteins contain a diverse C-terminal antimicrobial domain connected to a conserved cathelicin-like N-terminal domain (the propiece) of approximately 100 residues. Cathelicidin peptides are considerably diverse in length, amino acid sequence and structure, and they have distinct functions and a diverse spectrum of activity and/or antimicrobial potency (e.g. abstract, p. 23, right column). Therefore, biological function of a protein was unpredictable from mere amino acid sequence at the time of the invention and even same family proteins having conserved region can show diverse biological functions. It would be unpredictable for the biological function of the proteins encoded by various unknown and unidentified nucleic acid sequence at the time of the invention. In view of such, one skilled in the art at the time of the invention would not know how to use the claimed isolated polynucleotide sequences.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the level of skill which is high, the working examples provided and scarcity of guidance in the specification, and the unpredictable nature of the art.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al., 1999, EST Accession No. AQ316736, computer printout pages 2-3.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Adams discloses a human genomic clone sequence, EST Accession No. AQ316736, which is 100% identical to base 1000-1697 of SEQ ID No. 1. The sequence of EST Accession No. AQ316736 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Adams.

10. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiyama et al., 2002, EST Accession No. AG157692, computer printout pages 3-4.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Fujiyama discloses a chimpanzee genomic DNA sequence, EST Accession No. AG157692, which is 98.8% identical to the base 519-1111 of SEQ ID No. 1. The sequence of EST Accession No. AG157692 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Fujiyama.

11. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by DOE joint genome institute, October 2003, GenEmbl Accession No. AC092383, computer printout pages 6-8.

Claims 1-3 and 6 are directed to an isolated MNTF associated polynucleotide comprising SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from

the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

DOE joint genome institute discloses a human genomic DNA sequence, GenEmbl Accession No. AC092383, which is 100% identical to the sequence of SEQ ID No. 1. The sequence of GenEmbl Accession No. AC092383 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by DOE joint genome institute.

12. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chau, M.W., 2001, GenEmbl Accession No. AR175907, computer printout pages 8-9.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Chau discloses a DNA sequence, GenEmbl Accession No. AR175907, which is 93.7% identical to the base 522-1466 of SEQ ID No. 1. The sequence of GenEmbl Accession No. AR175907 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least

one nucleotide selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Chau.

13. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chau, M.W., 2002, GenEmbl Accession No. BD084671, computer printout pages 11-12.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Chau discloses a DNA sequence encoding motoneuronotrophic factor, GenEmbl Accession No. BD084671, which is 93.7% identical to the base 522-1466 of SEQ ID No. 1. The sequence of GenEmbl Accession No. BD084671 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Chau.

14. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Morris DW, September 2003, Genseq Accession No. ACN44762, computer printout pages 7-9.

Claims 1-3 and 6 are directed to an isolated MNTF associated polynucleotide comprising SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1, said fragment comprises a 5'

terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Morris discloses a human genomic DNA sequence, Genseq Accession No. ACN44762, which is 100% identical to the sequence of SEQ ID No. 1. The sequence of Genseq Accession No. ACN44762 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Morris.

15. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chau, M.W., 1998, Geneseq Accession No. AAV11748, computer printout pages 10-12.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Chau discloses a DNA sequence encoding human MNTF-1927 DNA fragment, Geneseq Accession No. AAV11748, which is 93.7% identical to the base 522-1466 of SEQ ID No. 1.

The sequence of Geneseq Accession No. AAV11748 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Chau.

16. Claims 2, 3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Chau, M.W., 2001 (US Patent No. 6,309,877 B1) and computer printout pages 2-3.

Claims 2, 3 and 6 are directed to an isolated MNTF associated polynucleotide comprising a fragment of SEQ ID No. 1, said fragment comprises a 5' terminus selected from 1-1849 of SEQ ID No. 1 and is at least ten consecutive nucleic acid residues of SEQ ID No. 1 including a 3' terminus selected from residues 10-1859 of SEQ ID No. 1, or comprising a fragment of SEQ ID No. 1 containing at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3. Claim 6 specifies the polynucleotide fragment of claim 3 comprises at least one open reading frame.

Chau discloses the DNA sequence of human MNTF1-927 DNA fragment (SEQ ID No. 2) which encodes the MNTF1-F6 protein (SEQ ID No. 4), a vector containing said DNA sequence, and expression systems and associated hosts which contain said DNA sequence (e.g. column 3, lines 10-16). The sequence of SEQ ID No. 2 is 93.7% identical to base 522-1466 of the sequence of SEQ ID No. 1 of the instant invention. The sequence of SEQ ID No. 2 is at least ten consecutive nucleic acid residues of SEQ ID No. 1, contains at least **one nucleotide** selected from the listed nucleotide fragment listed in claim 3, and has an open reading frame. Thus, the claims are anticipated by Chau.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over either DOE joint genome institute, October 2003, GenEmbl Accession No. AC092383, computer printout pages 6-8 or Morris DW, September 2003, Genseq Accession No. ACN44762, computer printout pages 7-9 each in view of Chau, M.W., 2001 (US Patent No. 6,309,877 B1).

Claims 1, 15 and 16 are directed to an isolated MNTF associated polynucleotide comprising SEQ ID No. 1, an expression vector operably linked to the isolated polynucleotide, and an isolated host cell transformed with the expression vector.

DOE joint genome institute discloses a human genomic DNA sequence, GenEmbl Accession No. AC092383, which is 100% identical to the sequence of SEQ ID No. 1.

Morris discloses a human genomic DNA sequence, Genseq Accession No. ACN44762, which is 100% identical to the sequence of SEQ ID No. 1.

DOE joint genome institute and Morris do not specifically teach an expression vector containing the disclosed DNA sequence and a host cell transformed with said expression vector.

Chau discloses the DNA sequence of human MNTF1-927 DNA fragment (SEQ ID No. 2) which encodes the MNTF1-F6 protein (SEQ ID No. 4), a vector containing said DNA sequence, and expression systems and associated hosts which contain said DNA sequence (e.g.

column 3, lines 10-16). The sequence of SEQ ID No. 2 is 93.7% identical to base 522-1466 of the sequence of SEQ ID No. 1 of the instant invention. Chau teaches preparation of pGEX vector containing the DNA sequence of human MNTF-927 DNA fragment and transformation of E. coli strain DH5 with the pGEX vector for the expression of a recombinant protein (e.g. column 17, lines 26-54).

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to clone the DNA sequence disclosed by DOE joint genome institute or Morris into an expression vector for its expression in a host cell because cloning a DNA into a vector and transformation of a host cell with said vector were well known in the art and Chau teaches how to clone a DNA sequence into an expression vector and transformation of said vector into a host cell.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to express the gene in a host cell to obtain a recombinant protein as taught by Chau with reasonable expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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